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No. 01-188

In the Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PETITIONER

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING REVERSAL

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QUESTION PRESENTED

The United States will address the first question presented in the petition (at i):

Whether the federal Medicaid statute, 42 U.S.C. 1396 *et seq.*, allows a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations.[1]

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[1] This brief does not address the question whether the Maine Rx Program violates the Commerce Clause. The United States addressed that question in its brief (at 15-18) at the petition stage.

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INTEREST OF THE UNITED STATES

This case concerns whether the prior authorization provisions of the Maine Rx Program for prescription drugs are consistent with the federal Medicaid statute, which is administered by the Secretary of Health and Human Services. At the Court's invitation, the Solicitor General filed an amicus brief on behalf of the United States at the petition stage of this case.

STATEMENT

The Maine Rx Program at issue in this case is designed to encourage drug manufacturers to enter into a rebate agreement with the State that would require the manufacturer to provide a price discount for its drugs when purchased by *any* resident in the State. Absent such an agreement, the State, under its Medicaid program, will require Medicaid recipients to obtain prior authorization from the State before receiving an otherwise Medicaid-covered outpatient drug that is prescribed by a physician. This case presents the question whether the prior authorization feature of the

Maine Rx Program is unlawful under the Medicaid Act because it burdens Medicaid recipients in order to achieve goals unrelated to the Medicaid program.

A. Statutory Framework

1. The Medicaid program, established by Title XIX of the Social Security Act (the Medicaid Act), 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program that provides medical assistance to certain low-income individuals. *Harris* v. *McRae*, 448 U.S. 297, 301 (1980). The primary purpose of the Medicaid program is to "enabl[e] each State, as far as practicable under the conditions in such State, to furnish * * * medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. 1396.

In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the Centers for Medicare & Medicaid Services (CMS), which administers the federal Medicaid program on behalf of the Secretary of Health and Human Service (HHS). 42 U.S.C. 1396a. The state plan must specify, *inter alia*, the categories of individuals who will receive medical assistance under the plan and the specific kinds of medical care and services that will be covered. 42 U.S.C. 1396a(a)(10) and (17). If the plan is approved by the Secretary, the State is thereafter eligible for federal financial participation, *i.e.*, reimbursement by the federal government for a specified percentage of the amounts expended as medical assistance under the state plan. 42 U.S.C. 1396b(a)(1), 1396d(b).

States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. See *Alexander* v. *Choate*, 469 U.S. 287, 303 (1985). The Medicaid Act does, however, establish a number of prerequisites for approval of a state plan by the

Secretary. 42 U.S.C. 1396a(a)(1)-(65). Participating States are required to make medical assistance available to certain "categorically needy" persons. 42 U.S.C. 1396a(a)(10)(A)(i). At a State's option, a State may additionally make medical assistance available to "medically needy" persons. 42 U.S.C. 1396a(a)(10)(C); *Atkins* v. *Rivera*, 477 U.S. 154, 157-158 (1986). The Medicaid Act imposes income and resource limitations on many eligibility groups described in the statute. See, *e.g.*, 42 U.S.C. 1396a(a)(10)(A)(i)(IV), (VI) and (VII); 42 U.S.C. 1396b(f).

States are required to provide certain basic services, such as inpatient hospital care, to categorically needy individuals. 42 U.S.C. 1396a(a)(10)(A). The Act permits but does not require States to cover prescription drugs. 42 U.S.C. 1396d(a)(12). At least 44 States and the District of Columbia currently provide prescription drug coverage for categorically needy individuals, and 32 States and the District of Columbia provide such coverage for medically needy individuals. R. Schwalberg et al., *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights* 4 (Oct. 2001). During 1998, more than 19 million Americans received medical assistance for prescription drug purchases under state Medicaid plans, at a cost exceeding $13.5 billion. Staff of House Comm. on Ways & Means, 106th Cong., 2d Sess. *2000 Green Book* 927 (Comm. Print 2000) (*Green Book*); see also *id.* at 924 (Table 15-21). Drugs purchased by Medicaid recipients account for roughly 10% of all prescription drugs purchased in the United States. *Ibid.*; accord *Pharmaceutical Research & Mfrs. of Am. (PhRMA)* v. *Thompson*, 191 F. Supp. 2d 48, 53 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir. argument scheduled Dec. 5, 2002).

2. In 1990, Congress reviewed the prices being paid for prescription drugs under Medicaid. Congress determined that Medicaid was routinely paying more for prescription drugs than other large drug purchasers, particularly with

respect to single source drugs. H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). Congress concluded that "Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." *Ibid.* Congress therefore decided to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *Ibid.*

The rebate mechanism, enacted as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143, is codified as amended in 42 U.S.C. 1396r-8. State plans that provide medical assistance for covered outpatient drugs must comply with Section 1396r-8, and the Act generally prohibits federal financial participation "with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8." 42 U.S.C. 1396b(i)(10); see also 42 U.S.C. 1396a(a)(54) (requiring state plans to comply with Section 1396r-8). Section 1396r-8 provides that "[i]n order for payment to be available * * * for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement * * * with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer)." 42 U.S.C. 1396r-8(a)(1). The rebate obligation extends to all "covered outpatient drugs of the manufacturer * * * for which payment was made under the State plan." 42 U.S.C. 1396r-8(b)(1)(A).

If the drug in question is either a single source drug or an innovator multiple source drug, the rebate due on each unit paid for under the state plan is typically the difference between the average manufacturer price and the manufacturer's "best price," defined as the lowest price available from the manufacturer to any private purchaser or governmental entity within the United States, or 15.1% of average manufacturer price, whichever is greater. 42 U.S.C. 1396r-8(c)(1)(A), (B) and (C) and (c)(2). For other drugs, the rebate is 11% of average manufacturer price. 42 U.S.C. 1396r-8(c)(3). Drug manufacturers pay rebates to the state on a quarterly basis based on information provided by pharmacies as to the number of units of prescription drugs purchased by Medicaid recipients and covered under the state plan. 42 U.S.C. 1396r-8(b)(1)-(3), 1396r-8(k)(8). The state in turn reimburses pharmacies for the discounts that have been given on the manufacturers' prescription drugs. Approximately 500 manufacturers have entered into rebate agreements with the Secretary covering more than 56,000 drug products. 56 Fed. Reg. 7050 (1991) (setting forth rebate agreement between Secretary and drug manufacturers); http://cms.hhs.gov/medicaid/drugs/drughmpg.asp (list of manufacturers and drugs subject to Secretary's rebate agreement).

Once a drug manufacturer has entered into a rebate agreement with the Secretary (or, alternatively, a State) with respect to a covered outpatient drug, a State must cover that drug under the state plan unless the State complies with one of the provisions of the Medicaid Act that permits a State to exclude or restrict coverage. 42 U.S.C. 1396a(a)(54); H.R. Rep. No. 881, *supra*, at 97, 98. One such restriction is a prior authorization program. Section 1396r-8 provides that a state plan "may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available[,] * * * the approval of the drug before its dispensing for any medically accepted indication." 42 U.S.C. 1396r-8(d)(5). The Act further provides that "[a] State may subject to prior authorization any covered outpatient drug" only if the system providing for prior authorization "provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization," and "provides for the

dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation." 42 U.S.C. 1396r-8(d)(1)(A) and (d)(5).

A State may exclude or otherwise restrict the coverage of a drug where "the prescribed use is not for a medically accepted indication" or where expressly authorized by the rebate agreement. 42 U.S.C. 1396r-8(d)(1)(B)(i) and (iii). A State may also restrict from coverage or exclude altogether certain drugs, classes of drugs, or certain medical uses (such as drugs for weight control, fertility, hair growth, and smoking cessation). 42 U.S.C. 1396r-8(d)(1)(B)(ii) and (d)(2). In addition, a State may impose limits on minimum or maximum prescription quantities "to discourage waste," and "may address instances of fraud or abuse by individuals" as authorized under the Medicaid Act. 42 U.S.C. 1396r-8(d)(6).

In 1993, Congress amended Section 1396r-8 to permit States to maintain "formularies," *i.e.*, lists of covered drugs, under certain conditions. 42 U.S.C. 1396r-8(d)(1)(B)(iv). Under those amendments, an expert committee convened by the State may develop a formulary that excludes a covered drug "with respect to the treatment of a specific disease or condition" when "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome * * * over other drugs included in the formulary." 42 U.S.C. 1396r-8(d)(4)(C). A State must permit coverage of a "drug excluded from the formulary," however, "pursuant to a prior authorization program" that complies with the Act. 42 U.S.C. 1396r-8(d)(4)(D). Congress explicitly provided that "[a] prior authorization program established by a State * * * is not a formulary subject to the requirements" of Section 1396r-8. 42 U.S.C. 1396r-8(d)(4).

B. Proceedings in this Case

1. In 2000, the Maine Legislature enacted the Maine Rx Program to reduce prescription drug prices for all Maine residents. Me. Rev. Stat. Ann. tit. 22, § 2681 (West Supp. 2001) (Maine Act). The program is open to all Maine residents, and is designed to allow enrollees to purchase prescription drugs from participating Maine pharmacies at a discounted price. Pet. App. 3; Maine Act § 2681(2)(F).

Under the Maine Rx Program, the State will reimburse pharmacies for such discounts out of a fund that is supported solely by rebate payments that the State collects from drug manufacturers. Maine Act § 2681(9); Pet. App. 3. The Maine Act provides that a drug manufacturer that sells prescription drugs in Maine through any publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the State. Maine Act § 2681(3). The Act directs the Commissioner of the Maine Department of Human Services to negotiate the amount of the rebate required, taking into consideration the rebate calculated under the federal Medicaid rebate program administered by the Secretary of HHS (see 42 U.S.C. 1396r-8(a)-(c), discussed at pp. 4-5, *supra*) and using his best efforts to obtain an initial rebate amount equal to or greater than that amount. Maine Act § 2681(4).

The Maine Act provides for the public disclosure of the names of manufacturers that do not enter into rebate agreements with the State. Maine Act § 2681(7). And as particularly relevant here, the Act directs the Maine Department of Human Services to "impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers." *Ibid.*

2. Petitioner Pharmaceutical Research and Manufacturers of America (PhRMA) brought this action in the United States District Court for the District of Maine to challenge, *inter alia*, the prior authorization provisions of the Maine Rx Program as inconsistent with the Medicaid statute and the Commerce Clause. The district court entered a preliminary injunction barring the enforcement of the prior authorization

requirement against any drug manufacturer that does not enter into a rebate agreement with the State. Pet. App. 57-72.

The district court held that imposition of a prior authorization requirement under the state Medicaid program in this manner is inconsistent with the objectives of the federal Medicaid Act. Pet. App. 66-71. The court explained that the purposes of the Medicaid Act are to provide medical services, including prescription drugs, to individuals who are eligible for Medicaid, and observed that Congress thus has required that a state plan ensure that care and services will be provided in a manner consistent with "the best interests" of Medicaid's recipients. *Id.* at 67-68 (quoting 42 U.S.C. 1396a(a)(19)) (emphasis omitted). In the court's view, Maine may not impose a prior authorization requirement under its Medicaid program with respect to a drug manufacturer that does not enter into a rebate agreement covering persons who are not eligible for Medicaid, because Maine could not identify any Medicaid purpose that such a requirement would serve. *Id.* at 68. The court also concluded that the prior authorization provisions violate the Commerce Clause because "the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine." *Id.* at 66.

3. The court of appeals reversed and vacated the preliminary injunction. Pet. App. 1-53. After determining that petitioner has standing to sue (*id.* at 6-8), the court rejected its arguments on the merits. The court perceived "no conflict between the Maine Act and Medicaid's structure and purpose" because the Maine Act requires compliance with the Medicaid program's specific requirements for a prior authorization program. *Id.* at 11 (citing 42 U.S.C. 1396r-8(d)(5)). The court also rejected petitioner's argument that it would be necessary to invalidate Maine's prior authorization provisions if they advanced no Medicaid purpose, concluding

that the absence of a Medicaid purpose "does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program." *Id.* at 12-13.

In addition, however, the court concluded that the Maine Rx Program does serve Medicaid purposes. In particular, the court concluded that the Maine Rx Program "furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services,' 42 U.S.C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid." Pet. App. 13. The court noted that "there is some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." *Ibid.* The court then reasoned that, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." *Ibid.*

The court also rejected petitioner's contention that the Maine Act is unconstitutional under the Commerce Clause, concluding that it regulates activity that occurs in the State —the purchase of prescription drugs that triggers the rebate requirement, negotiation of rebate agreements, and prior authorization under the State's Medicaid program. Pet. App. 20- 23.

Judge Keeton filed a concurring opinion that stressed the difficulty of prevailing on a facial challenge. Pet. App. 31-53.

SUMMARY OF ARGUMENT

A. A State has broad discretion to subject any Medicaid-covered drug to prior authorization when such a requirement furthers the objectives of the Medicaid program. Congress passed the drug rebate provisions with an explicit grant of authority to "subject to prior authorization any

covered outpatient drug," as long as the State provides for a 24-hour response to a request for prior approval and for the dispensing of a 72-hour supply of the requested drug in an emergency situation. 42 U.S.C. 1396r-8(d)(1)(A) and (d)(5). Congress included those provisions to give States "the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990). A State accordingly may establish a prior authorization program in order to reduce Medicaid costs for prescription drugs.

A State may not, however, implement a prior authorization program in order to advance non-Medicaid related goals. The drug rebate provisions, and the prior authorization provisions in particular, are designed to allow the State to strike an appropriate balance between the interests of Medicaid recipients in receiving covered prescription drugs of their physicians' choice and the interests of the Medicaid program as a whole in reducing expenditures for prescription drugs. That purpose of balancing various interests is frustrated by the use of a prior authorization program to further objectives that are unrelated to the Medicaid program.

The Maine Rx Program is therefore invalid because it is not designed to serve the interests of the Medicaid program. The program is open to all residents, and was enacted to lower prescription drug costs for all Maine citizens, regardless of financial or medical need. In these circumstances, the Maine Rx Program undermines congressional intent that a State will tailor its prior authorization program to achieve Medicaid-related goals.

B. In other situations, States may be able to rely on provisions in their Medicaid programs to assist in obtaining prescription drug benefits or discounts for non-Medicaid recipients, if the Secretary determines that such state initiatives sufficiently serve the objectives of the Medicaid program.

The Act grants the Secretary the authority to approve "any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives" of the Medicaid program. 42 U.S.C. 1315(a). Under that authority, the Secretary has approved demonstration projects by a number of States, including Maine, that provide prescription drug coverage to limited non-Medicaid populations, such as the low-income elderly. Because the Secretary regards the State's funding of such programs "as expenditures under the State plan," 42 U.S.C. 1315(a)(2)(A), a State's payment for a prescription drug under a demonstration project triggers the obligation of drug manufacturers to pay rebates under the federal Medicaid Act. 42 U.S.C. 1396r-8(b)(1)(A).

States may also be able to obtain drug discounts for certain low-income, albeit non-Medicaid populations, by using a prior authorization program to encourage drug manufacturers to extend rebates for drugs purchased by those populations. The Secretary has determined that any such program must be submitted to the Secretary under his regulations governing state plan amendments. App., *infra*, at 48a. The Secretary has explained that in submitting such a proposed amendment, the State should be prepared to demonstrate that it will "further the goals and objectives of the Medicaid program," such as "by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible." *Id.* at 48a-49a.

ARGUMENT

A STATE MAY REQUIRE PRIOR AUTHORIZATION FOR PRESCRIPTION DRUGS UNDER ITS MEDICAID PROGRAM IN ORDER TO ACHIEVE COST SAVINGS OR TO FURTHER OTHER MEDICAID-RELATED GOALS

Under the federal Medicaid program, States have broad discretion to tailor their Medicaid programs to meet the particular needs of their residents and their budgetary and other circumstances. *Alexander* v. *Choate*, 469 U.S. at 303; *Wisconsin Dep't of Health & Family Servs.* v. *Blumer*, 122 S. Ct. 962, 976 (2002). Accordingly, the Court has "not been reluctant to leave a range of permissible choices to the States, at least where the superintending federal agency has concluded that such latitude is consistent with the statute's aims." *Id.* at 975. That range of permissible choices is not, however, without its limits, and in this case the prior authorization feature of the Maine Rx Program exceeds those limits because it is not specifically designed to further any Medicaid purposes.

The court of appeals held that the prior authorization feature of the Maine Rx Program is not "preempted" by the federal Medicaid Act. But here, as in *New York State Department of Social Services* v. *Dublino*, 413 U.S. 405 (1973), the court below used the word "preemption" in a "rather special sense," for this case does not involve a claim of preemption of "a wholly independent state program dealing with the same or a similar problem." *Id.* at 411 n.9. Rather, Medicaid (like the Aid to Families with Dependent Children program in *Dublino*) "is a federal statutory program," and Maine's imposition of a prior authorization requirement under its Medicaid program necessarily is carried out "as part of the implementation of [Medicaid], and [is] therefore not wholly independent of the federal program." *Ibid.* Accordingly, the question is whether the prior authorization

provision of the Maine Rx Program is within the scope of the broad discretion that Congress afforded the States in fashioning their Medicaid plans. The Secretary of Health and Human Services is responsible for approving state plans and for the overall administration of the Medicaid program, and his position regarding the validity of the feature of the Maine Rx Program that is tied to the State's implementation of the federal Medicaid program is entitled to considerable deference. See *Dublino*, 413 U.S. at 421; see also, *e.g.*, *Blumer*, 122 S. Ct. at 976.

As explained below, the prior authorization provision of the Maine Rx Program is not within the scope of Maine's discretion under the Medicaid Act. "Where coordinate state and federal efforts exist within a complementary administrative framework, and *in the pursuit of common purposes*, the case for federal pre-emption [is] a less persuasive one." *Dublino*, 413 U.S. at 421 (emphasis added). Here, however, the prior authorization feature of the Maine Rx Program does not purport and is not tailored to further a Medicaid-related objective, such as preserving scarce Medicaid resources by making prescription drugs more readily available to low-income people and thereby reducing the prospect that they will become eligible for Medicaid. The Maine Rx Program is open to all Maine residents, whether rich or poor. Its prior authorization feature therefore is not "in pursuit of common purposes" with the federal Medicaid program. *Ibid.* Or, put in more traditional preemption terms, the prior authorization feature of the Maine Rx Program "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of the federal Medicaid Act, *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941), because it imposes on Medicaid beneficiaries the burdens of a prior authorization requirement without serving a countervailing Medicaid-related purpose.

The Secretary of HHS, through CMS, has recently sent a letter to State Medicaid Directors setting forth the Secre-

tary's interpretation of 42 U.S.C. 1396r-8 in several respects relevant to the issues in this case. Letter from Dennis G. Smith, Dir. of CMS's Center for Medicaid and State Operations, to all State Medicaid Dirs. (Sept. 18, 2002) (SMD Letter), App., *infra*, 45a-50a. That letter explains, *inter alia*, that a State's imposition of a prior authorization requirement under its Medicaid program to encourage the payment of drug rebates for non-Medicaid beneficiaries would constitute a material change in the operation of the state plan that must be approved by the Secretary as an amendment to the State's Medicaid plan. *Id.* at 48a. That letter further explains that a State must make an adequate showing that such an amendment would sufficiently further Medicaid-related purposes. *Id.* at 48a-49a. Because the Secretary has not yet approved any such state plan amendment, any questions concerning the scope of the Secretary's authority in that regard are not ripe for judicial review and are not before this Court in the present case. Any such questions may be addressed in a concrete setting in a future case in the event the Secretary approves a particular state plan amendment.

A. The Prior Authorization Provision Of The Maine Rx Program Is Invalid Because It Is Not Designed To Further A Medicaid-Related Purpose

1. *A State May Require Prior Authorization For Prescription Drugs In Order To Achieve Cost Savings Under Its Medicaid Program*

a. Before 1990, States had routinely required prior authorization for prescription or dispensing of drugs in order to control Medicaid costs. 136 Cong. Rec. 30,515 (1990) (noting the absence of any "federal laws or regulations governing prior authorization programs"); accord *Medicaid Prescription Drug Pricing: Hearing on S. 2605 Before the Subcomm. on Health for Families and the Insured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 17 (1990)

(statement of Rep. Wyden). In enacting the drug rebate provisions of Section 1396r-8 in 1990, Congress did not intend to upset that practice. Section 1396r-8 thus expressly permits a State to "subject to prior authorization any covered outpatient drug," but only if the State provides, first, for a 24-hour response to a request for prior approval, and, second, for the dispensing of a 72-hour supply of the requested drug in an emergency situation. 42 U.S.C. 1396r-8(d)(1)(A) and (d)(5). Congress recognized that those provisions would continue to give States "the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101st Cong., 2d Sess. 98 (1990); accord *id.* at 95 (States "may * * * require prior authorization with respect to any of the prescription drugs which they elect to cover."), 98 ("[T]he bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs.").[2]

A State therefore has broad discretion to subject covered drugs to prior authorization in order to achieve cost savings for the Medicaid program, even though a prior authorization requirement may burden the ability of Medicaid recipients to obtain prescribed drugs. Such a program would further Congress's specific intent in enacting the prior authorization provisions to afford the States a mechanism to reduce Medicaid costs for prescription drugs, and would further the Act's requirement that state plans "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan * * *

[2] Section 4401(a)(3) of OBRA 1990, 104 Stat. 1388-143, provided that a State could not require prior authorization for new drugs approved by the Food and Drug Administration for a period of six months following FDA approval. In 1993, Congress deleted that restriction. Act of Aug. 10, 1993, Pub. L. No. 103-66, § 13602(a)(1), 107 Stat. 613.

as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A).

Applying those principles, the Secretary has approved state plan amendments submitted by Florida, Illinois, and Michigan, under which the State will generally require prior authorization under its Medicaid program for any drugs for which the drug manufacturer has not entered into a supplemental drug rebate agreement that provides for rebates for drugs prescribed to Medicaid beneficiaries in the State that are in excess of the rebates set forth in the manufacturer's rebate agreement with the Secretary.[3] Those initiatives "operate[] to drive down the cost of prescription drugs under the Medicaid program by providing drug manufacturers with a strong economic incentive to offer the state a supplemental rebate," which in turn "can directly improve the coverage and efficiency of the state Medicaid program." *PhRMA* v. *Meadows*, No. 02-10151J, 2002 WL 31000006 (11th Cir. Sept. 6, 2002), at *9; see SMD Letter, *infra*, 46a-47a ("A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with [Section 1396r-8] as well as the paramount purpose of the drug rebate provisions * * * to reduce the costs to the Medicaid program for prescription drugs.").

b. Petitioner has brought suits challenging the Florida and Michigan initiatives on two grounds. First, petitioner contends that a State lacks the authority to enter into a drug rebate agreement that supplements the national rebate agreement between the Secretary and the manufacturer, rather than supplanting the national agreement in that

[3] The Secretary currently is considering whether to approve similar state plan amendments submitted by Louisiana, Minnesota, Vermont, and West Virginia, and anticipates similar requests for approval from at least three other States.

State. Second, petitioner contends that the Florida and Michigan programs are not valid prior authorization programs, but rather in effect establish formularies that fail to comply with the requirement of 42 U.S.C. 1396r-8(d)(4)(C) that any drug excluded from a formulary be determined by an expert committee to lack "a significant, clinically meaningful therapeutic advantage * * * over other drugs included in the formulary."

Those contentions are without merit. Indeed, petitioner's challenge to Florida's plan amendment has been rejected by the Eleventh Circuit in *PhRMA* v. *Meadows*, *supra*.[4] The Act explicitly gives the Secretary the authority to approve a drug rebate agreement between a State and a drug manufacturer that sets forth the conditions on which Medicaid will make payment for a covered outpatient drug. 42 U.S.C. 1396r-8(a)(1) ("In order for payment to be available * * *, the manufacturer must have entered into and have in effect a rebate agreement * * * with the Secretary, on behalf of the States (except that, *the Secretary may authorize a State to enter directly into agreements with a manufacturer.*") (emphasis added). The Secretary accordingly has reasonably construed the Act—both in approving the amendments to the Florida, Illinois, and Michigan plans and in the September 18 letter to State Medicaid Directors—to permit a State to enter into either a separate rebate agreement or a supplemental rebate agreement with a drug manufacturer, as long as the result is to provide for drug rebates equal to or greater than the rebates set forth in the Secretary's national rebate agreement with the manufacturer. SMD Letter, *infra*, 45a-46a.

Furthermore, as the Secretary has also reasonably concluded, a State has the authority to establish a prior authori-

[4] Petitioner's challenge to the Michigan plan amendment has not yet been adjudicated. *PhRMA* v. *Thompson*, No. 02-CV-1306 (D.D.C. filed June 28, 2002).

zation program without meeting the requirements applicable to formularies. SMD Letter, *infra*, 47a. As discussed at pp. 14-15, *supra*, Congress in 1990 passed the prior authorization provisions of 42 U.S.C. 1396r-8(d)(1) and (5) to preserve the States' historic discretion to subject drugs to prior approval to contain Medicaid costs. The formulary provisions of Section 1396r-8(d)(4), which Congress added to the drug rebate provisions in 1993, gave States *additional* authority to exclude covered drugs, without modifying (much less detracting from) the States' well-established power to institute prior authorization programs. Indeed, when Congress added the formulary provisions of paragraph (d)(4), it expressly provided in the last sentence that "[a] prior authorization program established by a State under [42 U.S.C. 1396r-8(d)(5)] *is not a formulary* subject to the requirements of this paragraph." 42 U.S.C. 1396r-8(d)(4) (emphasis added); *PhRMA* v. *Meadows*, *supra*, at *3-*4, *10 (Section 1396r-8(d)(4)'s "unequivocal" last sentence "clarif[ies] that a prior authorization program and a formulary are distinct methods of restricting coverage of outpatient drugs"). The drug formulary provisions of the Act therefore furnish no basis for limiting a State's ability to establish a prior authorization program in order to obtain additional drug rebates for Medicaid recipients.

2. *The Medicaid Act Does Not Permit A State To Subject Drugs To Prior Authorization To Advance Goals Unrelated To The Medicaid Program*

A State's broad power to subject drugs to a prior authorization requirement, however, is not unlimited. In the Secretary's view, in addition to the Act's express 24-hour response and 72-hour emergency-supply requirements (42 U.S.C. 1396r-8(d)(5)), the Act contains a further limitation that a State will not use Medicaid's prior authorization provisions in order to further goals unrelated to the Medicaid program.

Congress did not intend that a State would require Medicaid beneficiaries to obtain prior authorization before obtaining covered prescribed drugs without serving *some* purpose related to Medicaid. For instance, Congress presumably did not intend that a State would leverage its Medicaid program to force a drug manufacturer to fund the State's transportation or education systems. Such an action would upset the balance struck by Congress in the prior authorization provisions between the interests of recipients in receiving medically necessary drugs and the interests of the States in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner. H.R. Rep. No. 881, *supra*, at 98.

The court of appeals therefore erred in perceiving "no basis for inflicting the 'strong medicine' of preemption on a state statute that * * * merely fails to directly advance the purpose of the [Medicaid] program." Pet. App. 13. Maine's imposition of a prior authorization requirement is "part of the implementation of [Medicaid]," which is supported by substantial federal financial participation, not a "wholly independent state program." *Dublino*, 413 U.S. at 411 n.9. A State's prior authorization law that burdens the ability of Medicaid recipients to obtain covered drugs while failing to serve Medicaid-related goals would frustrate Congress's objectives under Section 1396r-8(d)(1) to allow a State to subject drugs to prior authorization in order to further the economic and efficient administration of *the Medicaid program*. Such a state law therefore would not be "in the pursuit of common purposes," *Dublino*, 413 U.S. at 421, with the federal Medicaid Act.

A Medicaid-purpose requirement under Section 1396r-8(d) is reinforced by the structure of the Medicaid Act. States participating in Medicaid must provide such safeguards as may be necessary to assure that covered services will be provided in a manner consistent with "the best interests of [Medicaid] recipients." 42 U.S.C. 1396a(a)(19). That provi-

sion, of course, does not limit the ability of States to determine the "amount, duration, and scope" of optional Medicaid benefits under a state plan (42 U.S.C. 1396a(a)(10)(B) and (C)(i)), or to take other action expressly provided for under the Act, including subjecting drugs to prior authorization (42 U.S.C. 1396r-8(d)(1)). And the "best interests" provision must be read in light of the other provisions of the Act that, *inter alia*, require a State to provide such procedures as may be necessary "to safeguard against unnecessary utilization" of services and to assure that payments are consistent with "efficiency, economy, and quality of care." 42 U.S.C. 1396a(a)(30)(A). The provision does, however, signal Congress's intent that a State will not act contrary to the interests of Medicaid recipients as a whole in order to achieve goals *unrelated* to the Medicaid program.

3. *The Prior Authorization Provision Of The Maine Rx Program Is Invalid*

The Maine Rx Program is invalid because it burdens Medicaid recipients without advancing Medicaid goals. Under the Maine Act, the State "shall impose [the] prior authorization requirements in the Medicaid program" on any "nonparticipating" drug manufacturer that does not enter into a rebate agreement with the State for drugs dispensed to *non*-Medicaid patients. Maine Act § 2681(7). The State program thus on its face is designed to serve the State's *non-Medicaid* population by imposing a burden on the ability of *Medicaid* recipients to receive an otherwise covered outpatient drug that is prescribed by a physician. Pet. App. 17.

The court of appeals reasoned that the Maine Rx Program could be sustained as furthering some purpose "related to Medicaid" because there was "some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." Pet. App. 13. The state law, however, is not tailored to any Medicaid-related purpose of ensuring low-income individuals' ac-

cessibility to prescription drugs. The Maine Rx Program is open to all Maine residents, regardless of financial or medical need. *Id.* at 3; see 2000 Maine Acts, ch. 786 § A-5(2) ("It is the intent of the Legislature to provide access for *all* Maine citizens to medically necessary prescription drugs at the lowest possible prices.") (emphasis added). Nor does the Maine Act's statement of purposes reveal any Medicaid objective. *Id.* § A-5(3) (the law was enacted "to make prescription drugs more affordable for Maine residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare"). The Maine Rx Program thus undermines congressional intent that a State would not burden Medicaid recipients to achieve goals unrelated to the Medicaid program. See pp. 18-20, *supra*.[5]

The Maine Rx Program stands in contrast in this regard to a demonstration project that Maine has been conducting under the Secretary's special authority to approve an experimental state project that would permit non-Medicaid recipients to obtain drug discounts when the Secretary concludes that such a project "is likely to assist in promoting the objectives" of the Medicaid program. 42 U.S.C. 1315(a); see pp. 29-30, *infra*. The Maine demonstration project is specifically tailored to provide prescription drug discounts to financially needy non-Medicaid individuals with household incomes of

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[5] On October 5, 2000, Maine proposed implementing rules that would have required pharmacies to submit claims for reimbursement from the Maine Rx Program when "no other reimbursement option [is] available." J.A. 317. The proposed rules further stated that the Maine Rx Program "provides access to discounted prescription drugs only when the individual does not have a comparable or superior prescription drug benefit plan." J.A. 317. The proposed rules, however, contain no income limitations on eligibility, and set forth state residency as the only requirement for eligibility to participation in the Maine Rx Program. J.A. 311; see J.A. 307 ("The program allows *Maine residents* enrolled in the Program to purchase drugs at reduced cost.") (emphasis added).

up to 300% of the federal poverty level. See pp. 24-26, *infra*.[6] Maine residents who are eligible for benefits under this demonstration project would have no incentive to enroll in the Maine Rx Program because, according to CMS, the demonstration project appears to offer greater benefits. Thus, as a practical matter, the Maine Rx Program targets persons whose income is in excess of 300% of the federal poverty level. No Medicaid-related purpose is served by a state program focusing on that population. Especially in these circumstances, the Maine Rx Program exceeds a State's authority under Section 1396r-8(d) to subject drugs to prior authorization.

B. The Medicaid Act Does Not Prohibit A State From Relying On Provisions Of Its State Medicaid Plan To Promote The Availability Of Prescription Drug Benefits To Non-Medicaid Recipients If The Secretary Determines That Such An Initiative Would Further The Act's Objectives

The invalidity of the Maine Rx Program does not mean that States are powerless to invoke the Act's prior authorization provisions to enable non-Medicaid recipients to obtain more affordable drugs. The Medicaid Act affords the States broad latitude in implementing the Medicaid program, "at least where the superintending federal agency has concluded that such latitude is consistent with the statute's aims." *Blumer*, 122 S. Ct. at 975. Thus, the Act authorizes the Secretary to approve demonstration projects that require manufacturers to extend the Act's mandatory drug rebates to drugs purchased by individuals who are not otherwise eligible under Medicaid. In addition, a State may be able to demonstrate to the Secretary in a particular case that use of a prior authorization program under a state plan to benefit

[6] Currently, the federal poverty level under HHS's guidelines is $8860 for an individual and $18,100 for a four-member household. 67 Fed. Reg. 6932 (2002).

non-Medicaid populations is consistent with the purposes of the Medicaid program and therefore not prohibited.

1. The Secretary may authorize demonstration projects to provide Medicaid drug benefits to non-Medicaid eligible individuals

Nearly forty years ago, Congress recognized that the requirements of the Social Security Act "often stand in the way of experimental projects designed to test out new ideas." S. Rep. No. 1589, 87th Cong., 2d Sess. 19 (1962). Congress accordingly amended the Act to authorize the Secretary to approve "any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives" of various titles of the Act, including Title XIX, which governs the Medicaid program. 42 U.S.C. 1315(a). If the Secretary makes such a determination, he may "waive compliance with" any of the requirements of 42 U.S.C. 1396a, the provision that establishes the prerequisites for state Medicaid plans, "to the extent and for the period he finds necessary to enable such State * * * to carry out such project." 42 U.S.C. 1315(a)(1). The Secretary is also authorized, "to the extent and for the period prescribed by the Secretary," to regard any "costs of such project" that "would not otherwise be included as [state Medicaid] expenditures" "as expenditures under the State plan" that qualify for federal financial participation. 42 U.S.C. 1315(a)(2). As a matter of federal administrative policy, the Secretary will not approve a demonstration project unless it is budget-neutral with respect to the federal government, so that the federal government's costs over the life of the project do not exceed the contribution that the federal government would make to the State under the state Medicaid plan in the absence of the project. 59 Fed. Reg. 49,250 (1994). The Secretary has also stated that he will "[g]rant waivers to test the same or related policy innovations in multiple States," since "replication is a valid mecha-

nism by which the effectiveness of policy changes can be assessed." *Id.* at 49,249.

In a variety of contexts, the Secretary has approved demonstration projects under Medicaid to test the extension of benefits to certain individuals who are not otherwise eligible under Medicaid when the project is likely to assist in promoting the objectives of the Social Security Act. *E.g.*, http://www.cms.hhs.gov/medicaid/waivers/waivermap.asp (describing projects in Arkansas, Massachusetts, Minnesota, Missouri, Oregon, Rhode Island, Tennessee, and Wisconsin that extend managed care Medicaid benefits to certain non-Medicaid eligible individuals); http://www.state.me.us/bms/admin/sfy2000.pdf (describing Maine demonstration project that provides pharmacy and physician-assistant services to HIV-positive individuals with incomes not exceeding 250% of the federal poverty level).

As particularly relevant here, the Secretary also has authorized demonstration projects by a number of States to provide prescription drug coverage to limited non-Medicaid populations. Because the Secretary regards the costs of such projects "as expenditures under the State plan," 42 U.S.C. 1315(a)(2), a State's payment for a prescription drug under a demonstration project triggers the obligation of drug manufacturers to pay rebates under Section 1396r-8. 42 U.S.C. 1396r-8(b)(1)(A) (rebate payments must extend to "covered outpatient drugs * * * for which payment was made under the State plan").

Indeed, on January 18, 2001, the Secretary approved a demonstration project for Maine known as the "Maine Prescription Drug Discount Program" (now called the "Healthy Maine Prescriptions" or "HMP" program). The project consists of two components: (1) a "Low Cost Drugs for the Elderly or Disabled" (DEL) program, under which the State pays roughly 80% of certain prescription drug costs that exceed $1000 per year for elderly and disabled persons whose incomes do not exceed 185% of the federal poverty level, and

(2) a non-DEL component, under which the State pays two percent of the costs of non-DEL drugs purchased by persons with incomes below 300% of the federal poverty level.[7]

In addition to increasing the availability and affordability of prescription drugs to low-income individuals, Maine anticipated that its demonstration project would "provide important information on health status and utilization patterns of beneficiaries, as well as contribute to State public policy and planning." *PhRMA* v. *Thompson*, 191 F. Supp. 2d at 54. In approving the Maine project, the Secretary (acting through CMS's predecessor, the Health Care Financing Administration) determined that the project "is likely to assist in promoting the objectives of the Medicaid program." Letter from Robert A. Berenson, M.D., Acting Deputy Adm'r, to Kevin W. Concannon, Comm'r, Dep't of Human Servs. (Jan. 18, 2001). The Secretary explained that the program "would make prescription drugs more affordable to primarily low-income Maine residents who are not eligible for Medicaid," and "would allow these individuals to have affordable access to potentially life saving medicines." *Ibid.* The Secretary further explained that the inability to pay for needed pre-

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[7] Petitioner has brought suit challenging the non-DEL component of Maine's program, arguing, *inter alia*, that Maine's two-percent contribution to the project is an insufficient "payment * * * made under the State plan" to trigger the manufacturer's rebate obligations under 42 U.S.C. 1396r-8(b)(1)(A). Petitioner relies on the D.C. Circuit's decision in *PhRMA* v. *Thompson*, 251 F.3d 219 (2001), which invalidated a portion of a Vermont demonstration project in which Vermont provided a prescription drug benefit to certain populations where the costs to the State would be fully reimbursed by the amount owed by drug manufacturers under the Secretary's rebate agreement. *Id.* at 224 (holding that 42 U.S.C. 1396r-8(b)(1)(A) requires un-reimbursed "payments with state or federal funds appropriated for Medicaid expenditures"). A district court has rejected petitioner's challenge to the non-DEL component of Maine's demonstration project, holding that Maine's un-reimbursed two-percent contribution constitutes a "payment" under the federal Medicaid Act. *PhRMA* v. *Thompson*, 191 F. Supp. 2d 48, 62-63 (D.D.C. 2002), appeal pending, No. 02-5110 (D.C. Cir. argument scheduled Dec. 5, 2002).

scription drugs can have a serious impact on the health of low-income persons and that "[e]xpanded access to medically necessary drugs will make it much more likely that this category of individuals will be healthier and potentially able to remain not eligible for Medicaid." *Ibid.* The Secretary also determined that the program "would allow [CMS] to obtain valuable data regarding drug utilization patterns for these low-income individuals who previously did not have a prescription drug benefit." *Ibid.*

The Secretary has also approved similar Pharmacy Plus demonstration projects in Florida, Illinois, Maryland, South Carolina, and Wisconsin, that provide Medicaid prescription drug and primary care coordination benefits to low-income individuals, generally seniors with incomes less than 200% of the federal poverty level. As CMS has explained, those projects "will test how provision of a pharmacy benefit to a non-Medicaid covered population will affect Medicaid costs, utilization, and future eligibility trends," and may be budget-neutral by "reduc[ing] the costs the State incurs for State plan eligible groups through lesser service utilization, reduced period of Medicaid eligibility, and more effective pharmacy benefit management." http://cms.hhs.gov/medicaid/1115/rxfactsheet41202.pdf.[8]

For instance, Illinois explained in its demonstration project application to the Secretary that "every dollar spent on pharmaceutical coverage is associated with a significant reduction in hospital care expenditures." Illinois Dep't of Public Aid 1115 Demonstration Waiver Application at 1, 4 (July 31, 2001). Those "savings relate not only to the preventive nature of some pharmaceuticals, but also to the fact that inadequate coverage of this primary care benefit causes millions of low-income elderly to reduce their use of clinically essential medications." *Id.* at 1, 4-5. Illinois accordingly predicted that its demonstration project will, *inter alia*, "[r]educe the speed at which seniors 'spend down' and become entitled to all benefits available under the Medicaid program." *Id.* at 3.

[8] The Secretary has received applications for similar projects from Arkansas, Connecticut, Indiana, Maine, Massachusetts, and New Jersey.

Florida likewise explained in its application to the Secretary that, "[w]hile the demonstration includes individuals who are not currently eligible for Medicaid, this new population could become eligible for Medicaid through deterioration in their health status and reduced income due to high medical expenses." State of Florida, *Pharmacy Plus, A Demonstration Program Under Section 1115*, at 16 (June 6, 2002). Florida estimated that "approximately 5,800 aged individuals will be diverted each year from the Medicaid program" because a prescription drug benefit will "improve the value of primary care by preventing illness that otherwise would require hospital[ization] or institutionalization." *Id.* at 21. Florida further predicted that the drug benefit "will also relieve individuals of the financial burdens that are associated with pharmaceuticals, thereby allowing them to maintain current financial stability and become Medicaid eligible less quickly." *Id.* at 21-22; accord Letter from Wendy E. Warring, Comm'r Mass. Exec. Office of Health & Human Servs., to Melissa Harris, CMS (May 1, 2002), attaching Massachusetts Pharmacy 1115 Demonstration Waiver Request ("The cost reductions [under Medicaid] would be realized from a decrease in premature reliance on the Medicaid program due to avoidable deterioration in health conditions, reductions in utilization of community or institutional long-term care services, and delays in individual spend-downs into the Medicaid program.").

2. *The Secretary May Approve A State Plan Amendment That Would Impose A Prior Authorization Program Designed To Obtain Drug Discounts For Non-Medicaid Recipients If It Would Sufficiently Further Medicaid Objectives*

As discussed at pages 14-18, *supra*, the Medicaid program's drug rebate provisions permit States to implement a prior authorization program in order to secure prescription drug discounts for Medicaid recipients. States may also be able, consistent with the Medicaid program, to make drugs more affordable to certain non-Medicaid populations by subjecting drugs to prior authorization under Medicaid in order to encourage drug manufacturers to agree to offer prescription drug discounts for those populations.[9] The Secretary has not yet approved any such state initiatives.[10] The Secretary has determined, moreover, that any such initiatives would constitute a "['m]aterial change[] in State law, * * * policy, or in the State's operation of the Medicaid program'" and therefore would require an amendment to the state plan. 42 C.F.R. 430.12(c)(1)(ii). In light of that determination, the Secretary has advised State Medicaid Directors that any

[9] On July 31, 2002, the Senate passed Senate Bill No. S. 812, 107th Cong., 2d Sess., 148 Cong. Rec. S7651 (daily ed. July 31, 2002), which would amend Section 1396r-8 to provide that nothing in that provision prohibits a State from directly entering into a rebate agreement with a drug manufacturer nor from making prior authorization a condition of not participating in a rebate agreement in order to increase the affordability of outpatient prescription drugs for non-Medicaid eligible individuals.

[10] Contrary to petitioner's assertion in its brief in response to the United States' amicus brief filed at the certiorari stage (Supp. Br. 4 n.5), the Secretary did not approve an initiative by Michigan, which petitioner has challenged. That program requires drug manufacturers to extend supplemental drug rebates for drugs purchased by non-Medicaid individuals who are not eligible under Medicaid but fall below the poverty line, are elderly and fall near the poverty line, or are children with special diseases that are costly to treat. Mich. Opp. to Mot. for Prelim. Inj. at 10 n.5, *PhRMA* v. *Thompson*, *supra* (describing relevant non-Medicaid populations); note 4, *supra*.

State that wishes to establish a prior authorization program under the state plan in order "to secure drug benefits, rebates, or discounts for non-Medicaid populations" is expected to submit such a program for approval under the Secretary's regulations for approval of state plans and plan amendments. SMD Letter, *infra*, 48a; see 42 C.F.R. 430.10-430.18.[11] The Secretary has informed State Medicaid Directors that in submitting a plan amendment, "the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program." SMD Letter, *infra*, 48a-49a.

For instance, as a result of the eligibility restrictions under Medicaid, many genuinely lower-income persons do not meet Medicaid's eligibility requirements. As of 1998, only 40% of those persons with incomes below the federal poverty level were covered by Medicaid. *2000 Green Book* 902. A prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decrease the chance that such individuals will become Medicaid-eligible as either categorically or medically needy individuals, and thereby drain the State's scarce Medicaid resources. Upon an adequate showing, the Secretary could reasonably conclude that a proposed plan amendment that targeted a narrowly defined class of persons who have a low income but nonetheless are not eligible under Medicaid would sufficiently advance the interests of Medicaid program and its recipients "as a whole" to warrant approval. SMD Letter, *infra*, 49a. As the court below observed, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further

[11] Petitioner has not challenged the Maine Rx Program on the ground that it was not submitted to the Secretary for approval as an amendment to the State's Medicaid plan. There accordingly is no occasion in this case to consider whether petitioner would have a cause of action to challenge the Maine Rx Program on that ground.

into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." Pet. App. 13; see also pp. 25-27, *supra*.

There is no reason in this case, however, for the Court to consider the scope of the Secretary's authority in this regard. As discussed above, the Maine Rx Program at issue in this case was adopted without the approval of the Secretary. That program, moreover, is not tailored to serve low-income populations. For that reason, the provision of the Maine Rx Program that imposes a prior authorization requirement under the State's Medicaid program on drug manufacturers that have not entered into a drug rebate agreement does not sufficiently advance a Medicaid-related goal.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX A

1. Section 1315, of Title 18, U.S.C., provides in relevant part:

§ 1315. Demonstration projects

(a) Waiver of State plan requirements; costs regarded as State plan expenditures; availability of appropriations

In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of subchapter I, X, XIV, XVI, or XIX of this chapter, or part A or D of subchapter IV of this chapter, in a State or States—

(1) the Secretary may waive compliance with any of the requirements of section 302, 602, 654, 1202, 1352, 1382, or 1396a of this title, as the case may be, to the extent and for the period he finds necessary to enable such State or States to carry out such project, and

(2)(A) costs of such project which would not otherwise be included as expenditures under section 303, 655, 1203, 1353, 1383, or 1396b of this title, as the case may be, and which are not included as part of the costs of projects under section 1310 of this title, shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under the State plan or plans approved under such subchapter, or for administration of such State plan or plans, as may be appropriate, and

(B) costs of such project which would not otherwise be a permissible use of funds under part A of subchapter IV of this chapter and which are not

included as part of the costs of projects under section 1310 of this title, shall to the extent and for the period prescribed by the Secretary, be regarded as a permissible use of funds under such part.

In addition, not to exceed $4,000,000 of the aggregate amount appropriated for payments to States under such subchapters for any fiscal year beginning after June 30, 1967, shall be available, under such terms and conditions as the Secretary may establish, for payments to States to cover so much of the cost of such projects as is not covered by payments under such subchapters and is not included as part of the cost of projects for purposes of section 1310 of this title.

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2. Section 1396a of Title 42, U.S.C., provides in relevant part:

§ 1396a. State plans for medical assistance

(a) Contents

A State plan for medical assistance must—

* * * * *

(19) provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients;

* * * * *

(30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care

and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area;

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(54) in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1396r-8(k) of this title), comply with the applicable requirements of section 1396r-8 of this title;

* * * * *

3. Section 1396r-8 provides:

§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of para-

graph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) Effective date

Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

(3) Authorizing payment for drugs not covered under rebate agreements

Paragraph (1), and section 1396b(i)(10)(A) of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance

with a prior authorization program described in subsection (d) of this section, or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) Effect on existing agreements

In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) Limitation on prices of drugs purchased by covered entities

(A) Agreement with Secretary

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992.

(B) "Covered entity" defined

In this subsection, the term "covered entity" means an entity described in section 256b(a)(4) of this title.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates

If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply:

(i) Entities

Each covered entity shall inform the single State agency under section 1396a(a)(5) of this title when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) of this title with respect to a unit of any covered outpatient drug which is subject to an agreement under section 256b(a) of this title.

(ii) State agency

Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) of this section with respect to such a drug.

(D) Effect of subsequent amendments

In determining whether an agreement under subparagraph (A) meets the requirements of section 256b of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(E) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b of this title (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies

(A) In general

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(C) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total

number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1) of this section) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement, and

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1,

1990[1] for each of the manufacturer's covered outpatient drugs.

(B) Verification surveys of average manufacturer price

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a-7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(C) Penalties

(i) Failure to provide timely information

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in

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[1] So in original. Probably should be followed by a comma.

which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information

Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(D) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler,

prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section,

(ii) to permit the Comptroller General to review the information provided, and

(iii) to permit the Director of the Congressional Budget Office to review the information provided.

(4) Length of agreement

(A) In general

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer

A manufacturer may terminate a rebate agreement under this section for any reason. Any such

termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements

The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) of this title and master agreements described in section 8126(a) of title 38.

(C) Delay before reentry

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and

(V) after December 31, 1995, is 15.1 percent.

(ii) Temporary limitation on maximum rebate amount

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(C) "Best price" defined

For purposes of this section—

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section;

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program; and

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

(ii) Special rules

The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(3) Rebate for other drugs

(A) In general

The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) Applicable percentage defined

For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning—

(i) before January 1, 1994, is 10 percent, and

(ii) after December 31, 1993, is 11 percent.

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written

explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the

dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

(e) Treatment of pharmacy reimbursement limits

(1) In general

During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this sub chapter or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph(2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule

If a State is not in compliance with the regulations described in paragraph(1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations

This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

[(4)][2] Establishment of upper payment limits

HCFA shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

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[2] See 1993 Amendment note below.

(f) Repealed and redesignated

(1) Repealed. Pub.L. 103-66, title XIII, § 13602(a)(1), Aug. 10, 1993, 107 Stat. 613

(2) Redesignated (e)[(4)]

(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information;

(III) the DRUGDEX Information System; and

(IV) American Medical Association Drug Evaluations; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serius interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent

with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection[3] (1)(B)as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

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[3] So in original. Probably should be "paragraph."

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * *[4] licensed and actively practicing pharmacists.

[4] So in original.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section[5] (2)(B).

(ii) Application of standards as defined in section[5] (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers

[5] So in original. Probably should be "paragraph."

and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management

(1) In general

In accordance with chapter 35 of title 44 (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement

In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1396b(a)(3)(A)(i) of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's

request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) Omitted

(j) Exemption of organized health care settings

(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1396b(m) of this title, are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c) of this section.

(k) Definitions

In this section—

(1) Average manufacturer price

The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price

paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

(2) Covered outpatient drug

Subject to the exceptions in paragraph(3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 [21 U.S.C. 355] or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act [21 U.S.C. 355(j)];

(ii)(I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C. 331, 332(a), 334(a)]

to enforce section 502(f) or 505(a) of such Act [21 U.S.C. 352(f), 355(a)]; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. S 356].

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration

or a drug or biological[6] used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

(4) Nonprescription drugs

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

[6] So in original. Probably should be "biological product."

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the State during the period.

(ii) Innovator multiple source drug

The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug

The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception

Subparagraph (A)(1)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(1)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) Rebate period

The term "rebate period" means, with respect to an agreement under subsection (a) of this section, a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

APPENDIX B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

September 18, 2002

Dear State Medicaid Director:

This letter is to clarify issues related to supplemental drug rebate agreements and prior authorization of Medicaid covered outpatient drugs. A number of States have sought CMS approval of supplemental drug rebate agreements between a State and drug manufacturers with respect to Medicaid covered outpatient prescription drugs. Some of these States subject covered outpatient drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients.

Medicaid Supplemental Drug Rebate Agreements

States may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). The drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secre-

tary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a State and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if CMS determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that States that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.

We remind States that supplemental drug rebates must be "considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance" as required by section 1927(b)(1)(B) of the Act.

Prior Authorization Requirements Related to Supplemental Rebate Agreements

States may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients. Section 1927(d)(1)(A) of the Act permits States to subject any covered outpatient drug to a requirement of prior authorization as long as the State complies with the requirements set forth in section 1927(d)(5). A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to

reduce the costs to the Medicaid program for prescription drugs.

A prior authorization program does not need to comply with the requirements for restrictive formularies. The formulary provisions of section 1927(d)(4) were added to the drug rebate provisions in 1993 to give States additional authority to implement restrictive formularies. Congress passed paragraph (d)(4) expressly stating that "[a] prior authorization program established by a State under [section 1927(d)(5)] is not a formulary subject to the requirements of this paragraph."* Furthermore, since concerns related to drug use, monitoring, waste, fraud or abuse are separately and independently addressed by the procedures authorized by sections 1927(d)(6) and 1927(g), a prior authorization program need not be limited to those concerns. The Act affords States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.

The operation of a prior authorization program used to negotiate drug discounts for the Medicaid population is a significant component of a State plan. We would therefore expect that a State that does not currently have an approved prior authorization State plan amendment, and that seeks to undertake such a program, would submit to CMS for review a State plan amendment incorporating the program's prior authorization requirements, while simultaneously seeking

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* Of course, the formulary provisions of section 1927(d)(4) continue to apply if a State chooses to make judgments about the therapeutic advantages of a drug excluded from a formulary, and the State plan must permit coverage of any such drug pursuant to a prior authorization program that complies with section 1927(d)(5).

CMS's authorization for its proposed separate or supplemental rebate agreement. A State that has an approved State plan amendment governing prior authorization requirements, but which seeks for the first time to use its prior authorization authority to negotiate drug discounts for the Medicaid program, must amend its State plan to refer to the separate or supplemental rebate agreement and submit its proposed rebate agreement for CMS authorization.

Non-Medicaid Supplemental Rebates and Medicaid Prior Authorization

A number of States secure prescription drug benefits, rebates, or discounts for *non-Medicaid* populations by linking such benefits to a Medicaid prior authorization program. The Act does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases. However, the establishment of a prior authorization program for Medicaid covered drugs to secure drug benefits, rebates, or discounts for non-Medicaid populations is a significant component of a State plan and we would therefore expect that a State would submit such a program for CMS review under the State plan process. Similarly, the use of any pre-existing prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid populations would constitute a "[m]aterial change[] in State law, . . . policy, or in the State's operation of the Medicaid program" and we would therefore expect that a State would submit a plan amendment to CMS for review. (See section 430.12(c)(1)(ii) of the regulations.) In submitting such a State plan amendment, the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and

objectives of the Medicaid program. A State could make such a demonstration by submitting appropriate evidence that its prior authorization requirement is designed to increase the efficiency and economy of the Medicaid program. A State could demonstrate that its prior authorization requirement furthers Medicaid goals and objectives by submitting appropriate evidence that the requirement sufficiently benefits the Medicaid population as a whole by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible.

If you have any questions regarding CMS policy relating to supplemental drug rebate agreements or prior authorization programs, please direct them to Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

Dennis G. Smith
Director

cc:

CMS Regional Administrators

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